DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
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Silver Spring, MD 20993-0002

October 23, 2014

Lepu Medical Technology (Beijing) Co., Ltd.
c/o Ms. Erin Badali
Sr. Regulatory Operations Associate
Vascular Solutions, Inc.
6464 Sycamore Court North
Minneapolis, Minnesota 55369

Re: K142359
Trade/Device Name: Vasc Band Hemostat
Regulation Number: 21 CFR 870.4450
Regulation Name: Vascular Clamp
Regulatory Class: Class II
Product Code: DXC
Dated: August 26, 2014
Received: August 27, 2014

Dear Ms. Badali,

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-

related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

for Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K142359

Device Name: Vasc Band hemostat

Indications for Use:

The Vasc Band hemostat is a compression device to assist hemostasis of arterial, venous and hemodialysis percutaneous access sites.

Prescription Use ___X____ (Part 21 CFR 801 Subpart D)	AND/OR	Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

2 510(k) Summary

[As required by 21 CFR 807.92]

Date Prepared: August 22, 2014

510(k) Number: _____

Submitter's Name / Contact Person

Manufacturer
Lepu Medical Technology (Beijing) Co., Ltd.
No. 37 Chaogian Road
Beijing, Changping District, CH 102200
Establishment Registration # 3008002401

Regulatory Correspondent
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General Information

Trade Name	Vasc Band
Common / Usual Name	hemostat
Classification Name	870.4450, DXC – Clamp, vascular, Class II
Predicate Device(s)	K111837 – Radial Artery Compression Tourniquet, Lepu Medical K081740 – HemoBand, Hemoband Corporation

Device Description

Vasc Band hemostat (Vasc Band) is a compression device that applies mechanical pressure to achieve hemostasis of vascular access sites. Vasc Band consists of an adjustable retention strap, inflatable compression balloon, inflation tube, and an inflation valve. A 22 ml inflation syringe is also included with the device. Vasc Band is available in five band lengths: 21 cm, 24 cm, 27 cm, 29 cm, and 37 cm.

Intended Use / Indications

The Vasc Band hemostat is a compression device to assist hemostasis of arterial, venous and hemodialysis percutaneous access sites.

Technological Characteristics

Vasc Band has the same intended use as the predicate devices and the same indications for use statement as HemoBand. Vasc Band has the same materials of construction as the predicate Radial Artery Compression Tourniquet and is similar in design as both devices are sterile compression bands that use an inflatable balloon to apply pressure at an access site to achieve hemostasis. Vasc Band is available in a wider range of lengths than the predicate devices.

Substantial Equivalence and Summary of Studies

Technological differences between the subject and predicate devices have been evaluated through bench tests to provide evidence of Vasc Band substantial equivalence. Vasc Band is substantially equivalent to the specified predicate devices based on comparison of the device functionality, technological characteristics, and indications for use. The device design has been verified through balloon pressure and band size tests.

Results of the verification tests met the specified acceptance criteria and did not raise new questions of safety or effectiveness. Therefore, Vasc Band is substantially equivalent to the predicate devices.